

REMARKS

Amendments to the claims have been made to respond to the issues and concerns raised in the Office Action, to clarify aspects in the specification and claims, and to refine claim language. The amendments are believed to be consistent with the disclosure originally filed. The amendments also have been particularly presented to avoid, where applicable, any admission or estoppel, generally, negatively affecting the scope of protection provided by the disclosure and claims of the present application, and also in a manner that avoids prosecution history estoppel, limitation of the scope of equivalences, or the like. The Applicant amends claims 137 and 145. Claims 1-44 and 52-135 have been cancelled. Thus, claims 45-51 and 136-145 remain in this application and are believed in a condition for allowance.

As a preliminary matter, the Applicant notes that many of the issues and concerns related to the present case present complex and intertwining considerations. Accordingly, in the event questions remain, the Applicant requests the opportunity to pursue an interview to resolve any issues or concerns.

With respect to the informality concerns raised by the Office Action regarding claims 137 and 145, please note the Applicant has amended these claims as suggested.

With respect to claims 45-47, 49-51, 136-140, and 142-145, the Office Action raises obviousness concerns under 35 U.S.C. § 103, citing Rens, Wilhelm, and Rath. Regarding the combination of Rens and Wilhelm, it is suggested that while Rens does not specifically exemplify applying its sorting method to equine sperm, Wilhelm teaches the use of equine sperm for the purpose of artificial insemination. We respectfully disagree. First, a review of Wilhelm indicates that nowhere are equine sperm used for artificial insemination. Rather, as stated on pages 321, 322, and 326, the purpose of Wilhelm is to determine if certain kinds of liposomes protect equine sperm from damage during cooling and freezing processes. Second, sorting equine sperm cells poses considerations that are different than those associated with other species. These considerations include the high

numbers of equine sperm cells required for effective artificial insemination and the delicate nature of equine sperm cells. For example, the specification at page 2, lines 26-28, discusses that natural insemination for equines involves billions of sperm and conventional techniques for equine artificial insemination routinely use 250 million to 500 million sperm. At page 2, lines 15-19, the specification relates that current flow cytometry techniques produce adequate numbers of sorted sperm in a reasonable amount of time for many species other than equines, including cattle. However, as discussed in the specification at page 2, lines 7-8, to make semen sexing a practical technique for equines, a lesser number of motile sperm is required for an insemination dose. Further, as discussed in the specification at page 4, lines 20-23, the equine conception process and/or the equine sperm cells themselves are more delicate than those of other species – especially bovines. In the context of flow cytometry, as discussed in the specification at page 5, lines 16-29, most sorted cells are able to physically withstand a variety of abuses. However, this is not the case for equine sperm cells, which may exhibit sensitivities to factors ranging from dilution problems to pressure stresses to the flow cytometer's need to distinguish each cell individually. As a result, this may represent a unique factor for equine sperm cells because flow cytometric sorting may have stressed the cells to the point of suboptimal performance, even though no visually discernable side-effects are displayed. Accordingly, the combination of Rens and Wilhelm does not render claims 45-47, 49-51, 136-140, and 142-145 obvious in as much as the combination does not teach using equine sperm cells for artificial insemination nor does it address the considerations that make sorting equine sperm cells different than those of other species.

Regarding the combination of Rens, Wilhelm, and Rath, it is suggested that the references teach collecting equine sperm into a skim milk solution. We respectfully disagree. The combination of references cited does not provide the requisite suggestion or motivation to combine the references as required by MPEP §2143.01. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP §2143.01; In Re Mills, 916 F.2d 680 (Fed. Cir. 1990). Simply because combining the elements is well within the ordinary skill of the art at the time of the claimed invention is not sufficient to

establish a prima facie case of obviousness. MPEP §2143.01; Ex Parte Levensgood, 28 USPQ2d 1300 (Bd. Pat. App & Inter. 1993). With attention to Wilhelm, the use disclosed for the SMEY extender is for freezing applications only. In fact, as discussed on page 322, Wilhelm affirmatively refers to SMEY as a “freezing extender”. Moreover, as discussed above, Wilhelm teaches no artificial insemination applications for its techniques. Importantly, Wilhelm suggests no further uses for SMEY other than as a freezing extender. Further, as noted in the Office Action, Rath teaches only collecting sex-sorted sperm into a TEST extender, and does not discuss a SMEY extender or freezing applications at all. Consequently, the purposes for which the extenders of Wilhelm and Rath are used – collection and freezing, respectively – are different, and there is no suggestion in the references that an extender used for one purpose would be suitable for the other. Accordingly, the combination of references does not provide the requisite suggestion or motivation to combine.

Additionally, as discussed in the specification at page 21, lines 4-13, the skim milk solution is used in the present case to minimize stresses upon cells and provide an easier reception as well, a purpose which nowhere is described in either Wilhelm or Rath. The specification further points out that the skim milk solution is used in this manner even though it itself was intended for a different purpose. Accordingly, the combination of Wilhelm and Rath further do not provide the requisite suggestion or motivation to use a skim milk solution for the purposes described the present case.

The Applicant notes that the above comments regarding the combination of Wilhelm and Rath with respect to a skim milk solution are equally applicable to the combination of Seidel, Wilhelm, and Rath, cited by the Office Action as raising obviousness concerns under 35 U.S.C. § 103 with respect to claims 45-51 and 136-145. Accordingly, the combination of Seidel, Wilhelm, and Rath also do not provide the requisite suggestion or motivation to use a skim milk solution in the manner of the present case.

With respect to claims 47 and 140, the Applicant notes these are dependent claims

and are allowable for the reasons discussed above with respect to the independent claims. However, the Applicant disagrees that the recitation of about 4% egg yolk encompasses 2% egg yolk. The Applicant notes that the recitation of about 4% egg yolk is a value, not a range, and therefore in fact does not encompass the value of 2% egg yolk. Pointedly, the 4% egg yolk value actually is twice as much as the 2% egg yolk value. Further, the Applicant respectfully disagrees that this value would have been obvious. Of course, once traversed, it is improper to maintain an allegation unsupported by evidence. As the courts have long stated:

[W]e reject the notion that judicial or administrative notice may be taken of the state of the art. The facts constituting the state of the art are normally subject to the possibility of rational disagreement among reasonable men and are not amenable to the taking of such notice. If evidence of the knowledge possessed by those skilled in the art is to be properly considered, it must be timely injected into the proceedings.

In re Eynde, 480 F.2d 1364 (CCPA 1973). Further, Examiners are even cautioned in their training materials against basing rejections on allegations of their personal impressions of what might be a design choice – essentially what might be obvious. To maintain such an allegation, evidence is necessary. Here, no combination of references suggests a skim milk solution containing about 4% egg yolk as a collection fluid. It therefore is incumbent upon the Office to provide evidence supporting its allegation that the stated values are in fact obvious.

With respect to claims 51 and 143, the Applicant notes these are dependent claims and are allowable for the reasons discussed above with respect to the independent claims. However, the Applicant disagrees that the stated pressure would have been obvious. As discussed above, once traversed, it is improper to maintain an allegation unsupported by evidence, and it therefore is incumbent upon the Office to provide evidence supporting its allegation that the stated pressure is in fact obvious. Moreover, contrary to the assertion of the Office Action, the stated pressure is not merely the discovery of an optimum or workable range by routine experimentation. As discussed above, equine sperm cells may be particularly delicate and sensitive to the stresses of flow cytometry. It may readily be appreciated that increasing the operating pressure of a flow cytometer acts to increase the

stresses to which cells are subjected. In as much as operating a flow cytometer at 50 psi represents a significantly higher pressure than may have been achieved before, the accompanying stresses may have been thought great enough to cause damage, impair effectiveness, or possibly even kill the sorted sperm cells. This effect may even be more pronounced for equine sperm cells, given their particularly delicate nature. In this manner, it may be appreciated that operating a flow cytometer at ever-increasing pressures is not merely a case of determining an optimum range. Rather, one must account and compensate for the increased stresses that are produced by such operation. Accordingly, the fact that the present invention allows a flow cytometer to be operated at 50 psi and still establish separated sperm cells capable of successful fertilization may be an unexpected result. The Applicant further notes that if the Office has further concerns with respect to claims 51 and 143, affidavit support is available to further discuss and augment the foregoing comments.

With respect to claims 136-137 and 144-145, the Applicant notes these are dependent claims and are allowable for the reasons discussed above with respect to the independent claims. However, the Applicant disagrees that the stated quantities and volumes would have been obvious. As discussed above, once traversed, it is improper to maintain an allegation unsupported by evidence, and it therefore is incumbent upon the Office to provide evidence supporting its allegation that the stated quantities and volumes are in fact obvious. Moreover, it should be noted that individual mammal species have varying thresholds for the quantity of sperm typically required to successfully complete artificial insemination, as discussed in the specification at page 21, line 26. For equines, as discussed in the specification at page 2, lines 1-4, a number of sperm from 250 million to 500 million has been presumed necessary. However, this threshold is unique to equines and is not the threshold that may be used in other mammal species. In this manner, it can be seen that the threshold values for other mammal species are meaningless for equines, and using them in order to make judgments about the correct numbers for use in equines is inapposite. Consequently, the values of Rens for bovines and Rath for porcine are inapplicable to the present case and may not be relied upon for making an obviousness determination.

Further, the combination of references do not provide one of ordinary skill in the art a reasonable expectation of successfully making the invention at the time the invention was made. MPEP §2143.02. Where the prior art provides only a general approach as to the particular form of the claimed invention or how to achieve it, the invention is not obvious, but only obvious-to-try. In Re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). With attention to Rens and Rath, flow cytometry is used to separate bovine and porcine sperm. However, the application of flow cytometry to equine sperm poses an additional problem – the fact that flow cytometers are not fast enough to sort the 250 million sperm typically required to successfully perform equine artificial insemination while maintaining sperm viability, as discussed in the specification at page 2, lines 3-13. This problem is not present in bovine and porcine applications and therefore is not dealt with by Rens and Rath. Also, this problem is beyond the ordinary skill in the art, because it would require from the ordinary artisan more inventive effort than merely determining the optimum quantities and volumes for an equine artificial insemination sample. Therefore, with respect to the references cited and the ordinary skill in the art, and as discussed in the specification at page 2, lines 19-25, only the present case teaches techniques that allow for successful equine artificial insemination with low numbers of equine sperm, which makes possible the use of flow cytometry to separate sperm in equine applications. Accordingly, while Rens and Rath may suggest that it would be desirable to use flow cytometry in an equine context, they do not teach techniques for accomplishing this goal and therefore suggest only that it would be obvious to try. Additionally, it is worth noting that in In Re O'Farrell, as discussed in MPEP §2145, the court upheld a finding of obviousness because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful. As discussed above, neither Rens nor Rath address any of these considerations. Consequently, their combination provides no basis for rendering as obvious claims 136-137 and 144-145.

The Applicant notes that the above comments regarding claims 136-137 and 144-145 are equally applicable to the combination of Seidel and Rath, wherein Seidel is cited for using bovine sperm. The Office Action cites the combination of Seidel and Rath as raising obviousness concerns under 35 U.S.C. § 103 with respect to claims 136-137 and 144-145. Consequently, the combination of Seidel and Rath provides no basis for rendering as obvious claims 136-137 and 144-145.

With respect to claims 48 and 141, the Office Action raises obviousness concerns under 35 U.S.C. § 103, citing Rens, Wilhelm, Rath, and Catt. The Applicant notes these are dependent claims and are allowable for the reasons discussed above with respect to the independent claims. Additionally, the combination of Rens and Wilhelm is discussed above as not teaching the use of equine sperm cells for artificial insemination nor addressing the considerations that make sorting equine sperm cells different than those of other species. Moreover, the combination including Catt does not provide the requisite suggestion or motivation to combine the references as required by MPEP §2143.01. Further case law and MPEP sections dealing with this point are set forth above. With attention to Catt, it is noted that a HEPES-buffered medium is used only in conjunction with sorting ram and boar sperm, and that a HEPES-buffered medium is not used as a sheath fluid. Importantly, no combination of the references suggests that using a HEPES-buffered medium would confer a particular advantage when used as a sheath fluid for equine applications. With respect to the references cited, only the present case recognizes such an advantage. As discussed in the specification at page 20, lines 26-30, the fact that a HEPES-buffered medium works well for equine applications is surprising not only because it is not the same type of buffer as may be used in bovine applications, but because it was originally developed for a bovine application. Further, as discussed in the specification at page 20, lines 16-25, the use of a HEPES-buffered medium as a sheath fluid not only in the context of flow cytometry parameters, but rather also in the context of equine sperm cell and equine artificial insemination parameters, reduces the flow cytometer sorting stresses by minimizing the changes in chemical environment experienced by equine sperm cells among pre-sort, sort, and post-sort environments. Accordingly, the combination of references cited not only fails to teach actual use of a

HEPES-buffered medium as a sheath fluid for sorting equine sperm cells in a flow cytometer, but also entirely ignores the reason why it is beneficial to do so, as is set forth in the present case. The combination of references therefore provides no basis for supporting an obviousness finding with respect to claims 48 and 141.

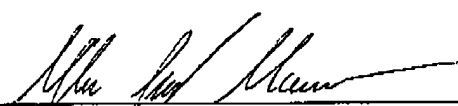
The Applicant, having addressed each of the concerns raised in the Office Action, respectfully requests reconsideration and withdrawal of the rejections and objections to the application. Allowance of claims 45-51 and 136-145 is requested at the Examiner's earliest convenience.

Dated this 13 day of January, 2005.

Respectfully submitted,

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